

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Michael D. Laufer CONFIRMATION NO.: 3758
SERIAL NO.: 10/735,349
FILING DATE: 12/11/2003
TITLE: Fat Removal and Nerve Protection Device and Method
EXAMINER: Stephens, Jacqueline F.
ART UNIT: 3761

**Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

APPEAL BRIEF

Dear Sir:

This paper is in support of the Notice to Appeal filed February 14, 2011.

It is respectfully submitted that the fee paid for the appeal brief filed September 17, 2009, be applied to this appeal brief. Therefore, no appeal brief fee is currently fee. However, in case this is incorrect and a fee is deemed due, authorization is hereby granted to charge said fee to our deposit account no. 50-3557.

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REAL PARTY IN INTEREST

Tony R. Brown, an individual.

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

Claims 1-54 and 61-91 have been canceled.

Claims 55-60 and 92-112 have been finally rejected and are on appeal.

STATUS OF AMENDMENTS

A reply to Final Office Action without amendment was February 14, 2011, and considered. All amendments have been entered.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention relates to surgical tools used to remove fatty tissue. One particular application is the removal of fatty tissue from the surface of an organ in order to provide access to the surface for surgical procedures. In the case of coronary bypass surgery, for example, often a layer of fatty tissue must be removed from around the heart to expose the myocardial tissue that is to be treated. The procedure is delicate and must take care not damage important arteries, veins and nerves that may be present, to avoid injury or death.

Claim 55 is directed to a method for removing fatty tissue while protecting nerves, and is best explained with reference to FIGS. 26-33. The method includes exposing a portion of the fatty tissue (¶ [0117], l. 2; ¶ [0120], l. 2; ¶ [0126], l. 2), pressing the fatty tissue (¶ [0117], ll. 3-4; ¶ [0120], ll. 3-4; ¶ [0126], ll. 3-4) with a non-convex surface (screen 1020, FIGS. 27 and 29; screen 1106, FIGS. 30 and 31; plate 1206, FIGS. 32 and 33) having at least one hole (1022, FIG. 27; 1022, FIG. 29; 1108, FIG. 30; 1210, FIG. 33), extruding fat through the at least one hole (¶ [0117], l. 4; ¶ [0120], ll. 4-5; ¶ [0126], ll. 3-4), the hole being dimensioned to allow fat cells to extrude through while preventing nerves from passing therethrough (*see* ¶ [0116], and ¶ [0127], ll. 2-4), and cutting, using a blade (¶ [0079], l. 4; ¶ [0081], l. 6; ¶ [0082], l. 4; ¶ [0083], l. 7, etc.), the fat that has extruded through the hole on a side of the surface opposite the fatty tissue (¶ [0083], ll. 5-7; ¶ [0117], ll. 4-7; ¶ [0120], l. 7; ¶ [0126], l. 5).

Claim 95 is also directed to a method of removing fatty tissue while protecting nerves, and includes exposing a portion of said fatty tissue (¶ [0117], l. 2; ¶ [0120], l. 2; ¶ [0126], l. 2), pressing the fatty tissue (¶ [0117], ll. 3-4; ¶ [0120], ll. 3-4; ¶ [0126], ll. 3-4) with a non-convex

surface (screen 1020, FIGS. 27 and 29; screen 1106, FIGS. 30 and 31; plate 1206, FIGS. 32 and 33) having at least one hole (1022, FIG. 27; 1022, FIG. 29; 1108, FIG. 30; 1210, FIG. 33), extruding fat through the at least one hole (§ [0117], l. 4; § [0120], ll. 4-5; § [0126], ll. 3-4), the hole being dimensioned to allow fat cells to extrude through while preventing nerves from passing therethrough (*see* § [0116], and § [0127], ll. 2-4), and cutting, using a shearing member (§ [0079], l. 4), fat that has extruded through said hole on a side of said surface opposite said fatty tissue (§ [0083], ll. 5-7; § [0117], ll. 4-7; § [0120], l. 7; § [0126], l. 5).

Claim 104 is also directed to a method of removing fatty tissue while protecting nerves, and includes exposing a portion of said fatty tissue (§ [0117], l. 2; § [0120], l. 2; § [0126], l. 2), pressing the fatty tissue (§ [0117], ll. 3-4; § [0120], ll. 3-4; § [0126], ll. 3-4) with a non-convex surface (screen 1020, FIGS. 27 and 29; screen 1106, FIGS. 30 and 31; plate 1206, FIGS. 32 and 33) having at least one hole (1022, FIG. 27; 1022, FIG. 29; 1108, FIG. 30; 1210, FIG. 33), extruding fat through the at least one hole (§ [0117], l. 4; § [0120], ll. 4-5; § [0126], ll. 3-4), the hole being dimensioned to allow fat cells to extrude through while preventing nerves from passing therethrough (*see* § [0116], and § [0127], ll. 2-4), and cutting, using a scraper (§ [0079], l. 4), fat that has extruded through said hole on a side of said surface opposite said fatty tissue (§ [0083], ll. 5-7; § [0117], ll. 4-7; § [0120], l. 7; § [0126], l. 5).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 55-60 and 95-100 are anticipated under 35 U.S.C. § 102(e) by U.S. Pat. Pub. No. 2003/0176851 (Bass; hereinafter, "Bass").

Whether claims 92-94 and 101-103 are unpatentable under 35 U.S.C. § 103(a) over Bass.

Whether claims 104-112 are unpatentable under 35 U.S.C. § 103(a) over Bass in view of U.S. Pat. No. 6,071,260 (Halverson; hereinafter, "Halverson").

ARGUMENT

Rejection of Claims 55-60 and 95-100 Under 35 U.S.C. § 102(e)

Claims 55-60

Claim 55 is a method claim reciting the step of “cutting, using a blade.” This feature is not disclosed in Bass. The Examiner states in the Advisory Action that Bass uses “a blade shaped instrument” and “teaches cutting fat with an electrocautery cutting element.” The Examiner also alleges, incorrectly, that Applicants’ claim 57 states that the step of cutting “‘further comprises cutting said fat with an electrocautery cutting element.’ ” In fact claim 57 was amended in the response filed April 6, 2010, to its present form, to remove the above-quoted language, and now reads:

57. A method in accordance with Claim 55, further comprising cauterizing fat that has extruded through said hole on a side of said surface opposite said fatty tissue.

First, Appellants respectfully submit that cutting using a blade is not the same as cutting using a blade shaped instrument, or cutting with an electrocautery cutting element. The fact that Bass’ electrocautery element may be shaped like a blade does not make cutting with it the same as cutting with a blade. Cutting with a blade is a mechanical action, while cutting with an electrocautery element relies on heating to weaken and sever tissue. Wikipedia, for instance, defines electrocauterization as “the process of destroying tissue using heat conduction from a metal probe heated by electric current.”

Second, Appellants’ invention envisions not only cutting through the mechanical action of a blade, to which claim 55 is directed, but also through electrocautery action, for example by heating the cutting blade to also perform electrocauterization. This approach of using a blade for both mechanical cutting and cauterization is the subject of claim 57, and finds support in

paragraph [0081] *et seq.* of the specification. Therefore claim 57 should not be construed as limiting claim 55 to electrocauterization, and as defining the cutting blade of claim 55 as an electrocautery device, as the Examiner does. Rather, claim 57 is intended to add electrocauterization action to the mechanical cutting action recited in claim 55.

Claims 95-100

Claim 95 is similar to claim 55, but recites “cutting, using a shearing member.” This feature is not disclosed in Bass and is not addressed by the Examiner, other than the statement in the final Office Action that “[e]lectrocautery is a known technique for cutting removing or shaving tissue as taught for example in Adams USPN 6503263 (col. 7, lines 28-34).”¹ It is unclear if this statement is intended as evidence of obviousness under 35 USC 103, in which case its use is improper in the anticipation rejection under 35 USC 102 that is applied. In any case it does not address the use of a shearing member, which, similar to the cutting member addressed above, relies on mechanical rather than heating action, and is in that sense also non-equivalent to the electrocautery device of Bass.

Rejection of Claims 92-94 and 101-103 Under 35 U.S.C. § 103(a)

Claims 92-94 and 101-103

Claims 92-94 and 101-103 are patentable over Bass at least by virtue of their dependence from the base claims discussed above.

In addition, claims 92-94 and 101-103 are directed to arrangements that are particularly well-suited for protecting nerves and blood vessels from the mechanical cutting actions envisioned. Recognizing that different compliance properties of nerves and blood vessels on the

¹ Office Action, # 4, last sentence of first paragraph.

one hand, and fatty tissue on the other, can be exploited, Appellants have arrived at specific hole dimensions that permit entry of fatty tissue into the device while precluding entry and damage to nerves and blood vessels. Such recognition and exploitation are more than mere discovery of optimum or workable ranges, as alleged in the Office Action.²

Rejection of Claims 104-112 Under 35 U.S.C. § 103(a)

Claims 104-112

Claim 104 recites, *inter alia*,

extruding fat through said at least one hole, the hole being dimensioned to allow fat cells to extrude through while preventing nerves from passing therethrough; and cutting, using a scraper, fat that has extruded through said hole on a side of said surface opposite said fatty tissue.

The Office Action acknowledges Bass' failure to disclose, teach or suggest the use of a scraper, and proposes a combination of with Halverson to cure this defect. Specifically, the Office Action reasons:

Halverson teaches scraping can be used in conjunction with ultrasonic methods. One having ordinary skill in the art at the time the invention was made would have been motivated to incorporate scraping since it provides an alternative or more thorough method of removing fat material when used in conjunction with ultrasonic methods.

Appellants respectfully maintain that a combination of the electrocauterization approach of Bass with the scraping approach of Halverson is unworkable. The electrocauterization element of Bass, consisting of electrode pair 22, 24, is disposed inside the cannula 12. Placing

² Id., #5, last sentence.

the scraper on probe 25 of Halverson inside the cannula as well would deprive it of the relative motion between the scraper and the fat tissue that it is intended to cut. Without this relative motion, the scraper would be inoperative. In Halverson, the relative motion is provided by the surgeon as he/she moves the entire device 10, including the scraper on probe 25, in the patient. In Appellants' invention, relative motion is provided by for example rotating the scraper within the device.³ In Bass, relative motion is not necessary because the electrocauterization device is static in nature, relying on thermal energy to remove the fatty tissue. Thus the combination of teachings of Bass and Halverson is unworkable and the rejection based thereon is improper.

³ Paragraph [0079], last line: "Thus, upon rotation of the inner cannula within the outer cannula, blade 322 rotates adjacent to the inner surface of barrier 316, and cuts, shears, and/or scrapes any material from the inner surface of the barrier which extends into the space swept out by the blade."

CLAIMS APPENDIX

55. A method of removing fatty tissue while protecting nerves, comprising the steps of:
exposing a portion of said fatty tissue;
pressing said fatty tissue with a non-convex surface having at least one hole;
extruding fat through said at least one hole, the hole being dimensioned to allow fat cells
to extrude through while preventing nerves from passing therethrough; and
cutting, using a blade, fat that has extruded through said hole on a side of said surface
opposite said fatty tissue.
56. A method in accordance with Claim 55, wherein said step of extruding fat further
comprises the step of preventing nerves from passing through said at least one hole while
permitting blood vessels to pass therethrough.
57. A method in accordance with Claim 55, further comprising cauterizing fat that has
extruded through said hole on a side of said surface opposite said fatty tissue.
58. A method in accordance with Claim 55, further comprising heating said fatty tissue at a
time selected from the group consisting of prior to said cutting step, during said cutting step, and
both prior and during said cutting step.
59. A method in accordance with Claim 55, wherein said step of pressing said fat layer
further comprises pressing with a surface having at least one hole located on a distalmost end of
a wand.
60. A method in accordance with Claim 55, wherein said step of pressing said fat layer
further comprises pressing with a surface having at least one hole located proximal of a
distalmost end of a wand.
92. A method in accordance with claim 55, wherein the hole has a diameter R , and said fat is
extruded a distance D through the hole having a diameter R , the ratio D/R being about 1.0.

93. A method in accordance with claim 55, wherein the hole has a diameter R, said fat is extruded a distance D through the hole having a diameter R, and D is from 10% less than the diameter of a nerve to be protected to 6 mm.
94. A method in accordance with claim 55, wherein the hole has a diameter R, said fat is extruded a distance D through the hole having a diameter R, and R is from 10% less than the diameter of a nerve to be protected to 6 mm.
95. A method of removing fatty tissue while protecting nerves, comprising the steps of:
exposing a portion of said fatty tissue;
pressing said fatty tissue with a non-convex surface having at least one hole;
extruding fat through said at least one hole, the hole being dimensioned to allow fat cells to extrude through while preventing nerves from passing therethrough; and
cutting, using a shearing member, fat that has extruded through said hole on a side of said surface opposite said fatty tissue.
96. A method in accordance with Claim 95, wherein said step of extruding fat further comprises the step of preventing nerves from passing through said at least one hole while permitting blood vessels to pass therethrough.
97. A method in accordance with Claim 95, further comprising cauterizing fat that has extruded through said hole on a side of said surface opposite said fatty tissue.
98. A method in accordance with Claim 95, further comprising heating said fatty tissue at a time selected from the group consisting of prior to said cutting step, during said cutting step, and both prior and during said cutting step.
99. A method in accordance with Claim 95, wherein said step of pressing said fat layer further comprises pressing with a surface having at least one hole located on a distalmost end of a wand.

100. A method in accordance with Claim 95, wherein said step of pressing said fat layer further comprises pressing with a surface having at least one hole located proximal of a distalmost end of a wand.

101. A method in accordance with claim 95, wherein the hole has a diameter R, and said fat is extruded a distance D through the hole having a diameter R, the ratio D/R being about 1.0.

102. A method in accordance with claim 95, wherein the hole has a diameter R, said fat is extruded a distance D through the hole having a diameter R, and D is from 10% less than the diameter of a nerve to be protected to 6 mm.

103. A method in accordance with claim 95, wherein the hole has a diameter R, said fat is extruded a distance D through the hole having a diameter R, and R is from 10% less than the diameter of a nerve to be protected to 6 mm.

104. A method of removing fatty tissue while protecting nerves, comprising the steps of:
exposing a portion of said fatty tissue;
pressing said fatty tissue with a non-convex surface having at least one hole;
extruding fat through said at least one hole, the hole being dimensioned to allow fat cells to extrude through while preventing nerves from passing therethrough; and
cutting, using a scraper, fat that has extruded through said hole on a side of said surface opposite said fatty tissue.

105. A method in accordance with Claim 104, wherein said step of extruding fat further comprises the step of preventing nerves from passing through said at least one hole while permitting blood vessels to pass therethrough.

106. A method in accordance with Claim 104, further comprising cauterizing fat that has extruded through said hole on a side of said surface opposite said fatty tissue.

107. A method in accordance with Claim 104, further comprising heating said fatty tissue at a time selected from the group consisting of prior to said cutting step, during said cutting step, and both prior and during said cutting step.

108. A method in accordance with Claim 104, wherein said step of pressing said fat layer further comprises pressing with a surface having at least one hole located on a distalmost end of a wand.

109. A method in accordance with Claim 104, wherein said step of pressing said fat layer further comprises pressing with a surface having at least one hole located proximal of a distalmost end of a wand.

110. A method in accordance with claim 104, wherein the hole has a diameter R , and said fat is extruded a distance D through the hole having a diameter R , the ratio D/R being about 1.0.

111. A method in accordance with claim 104, wherein the hole has a diameter R , said fat is extruded a distance D through the hole having a diameter R , and D is from 10% less than the diameter of a nerve to be protected to 6 mm.

112. A method in accordance with claim 104, wherein the hole has a diameter R , said fat is extruded a distance D through the hole having a diameter R , and R is from 10% less than the diameter of a nerve to be protected to 6 mm.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

Please charge any additional required fee or credit any overpayment not otherwise paid or credited to our deposit account No. 50-3557.

Respectfully submitted,
NIXON PEABODY LLP

Dated: April 13, 2011

/Khaled Shami/
Khaled Shami
Reg. No. 38,745

NIXON PEABODY LLP
P.O. BOX 60610
PALO ALTO, CA 94306
TEL. (650) 320-7700
FAX. (650) 320-7701